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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/910,183

Applicant(s)

GRIFFITHS ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **SEQUENCE RULES**

1. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

### **CLAIM OBJECTIONS**

2. **Claims 1, 14 and 17** are objected to for the following minor informality.

All recitations of a sequence should be accompanied by the appropriate SEQ ID NO: X.

### **35 U.S.C. § 101**

3. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

### **CLAIM REJECTIONS - 35 U.S.C. § 101**

4. **Claims 17, 19-20** are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claim 17 is nonstatutory because it reads on a product of nature. Claims 19-20 are nonstatutory because "the use of" is not a patentable category under 35 U.S.C. § 101.

### **35 U.S.C. § 112- 2ND PARAGRAPH**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**CLAIM REJECTIONS under 35 U.S.C. § 112- 2ND PARAGRAPH**

**6.** **Claims 1-22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claims 1, 14 and 17** are indefinite because of the use of the phrase "comprising or consisting of". The transitional phrases "comprising" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including", "containing" or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Molculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). In contrast, the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."). Because the applicant has used the phrase "comprising or consisting of", the scope of the claimed invention is unclear. Note the examiner has interpreted these claims broadly(i.e. as if only the word comprising were recited instead of the phrase "comprising or consisting of").

**Claim 4** is indefinite because it is unclear what is intended by the phrase "amelogenin sex test". How does the allelic ladder claimed include an amelogenin sex test? Also, does the applicant intend for the allelic ladder to include the amplification products (i.e. alleles) from both the X and the Y chromosomes or just the Y chromosome. Please clarify what is intended.

**Claim 5** is indefinite because it is unclear what is intended by the phrase "the allelic ladders in the mixture includes at least 7 alleles". Does the applicant intend for the all of the allelic ladders in the allelic ladder mixture to comprise at least seven alleles or, in the alternative, does the applicant intend for at least one of the allelic ladders in the allelic ladder mixture to comprise at least seven alleles? Please clarify what is intended.

**Claim 11** is indefinite because it is unclear what is intended by the number listed in the table. Do these numbers represent the molecular weight, the number of basepairs, the number of repeat units, or the allelic designation? Please clarify.

**Claim 15** is indefinite because of the phrase "(for instance for paternity or maternity analysis)". Because these limitations are recited it is unclear if the applicant intends the phrase "a human under consideration" to be limited to individuals being tested for maternity or paternity, or if the scope is broader. Please clarify.

**Claim 18** is indefinite because it is written as if it is drawn to a product, however, it also indicates that it is dependent on Claim 16 a method claim. Therefore, it is unclear what is intended. Is the applicant claiming a product, or in the alternative, is the applicant claiming a further embodiment of the method wherein the alleles provided are further defined? In the prior art rejections which follow it has been assumed that the applicant intended Claim 18 to be dependent on Claim 17 rather than Claim 16. Please clarify.

**Claims 21 and 22** are unclear because they do not recite positive steps delimiting how these methods are to be practiced. Also in Claim 22 the phrase "the ladder of Claim 17" lacks proper antecedent basis in Claim 17. Note, that in claim 17 the applicant is claiming one or more alleles of a particular sequence, not an allelic ladder. Please clarify.

### 35 U.S.C. § 102

**7.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

**CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

- 8. Claim(s) 17** is/are rejected under 35 U.S.C. 102(a) as being anticipated by Barber et al. (1996).

**Claim 17** is drawn to one or more alleles comprising or consisting of a structure selected from a defined group which includes (TCTA)<sub>8</sub> and (AGAA)<sub>8</sub> or alleles at least 75% homologous thereto.

Barber et al. teach one or more alleles comprising or consisting of (TCTA)<sub>8</sub> and comprising or consisting of (AGAA)<sub>8</sub>. See Barber et al. Figures 1-2.

- 9. Claim(s) 17-18, and 22** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Schumm et al. [US Patent No. 5,599,666 (1997)].

**Claim 17** is drawn to one or more alleles comprising or consisting of a structure selected from a defined group which includes (TCTA)<sub>8</sub>, (AGAA)<sub>8</sub> or alleles at least 75% homologous thereto.

Schumm et al. teach one or more alleles comprising or consisting of (AGAA)<sub>8</sub> or alleles at least 75% homologous thereto. See Schumm et al., Table 1 (i.e. HUMCSF1PO and HUMVWFA31) and Figure 1 and 14.

**Claim 18** is drawn to an embodiment of the allelic ladder mixture of Claim 16?(17) wherein the alleles are provided purified from alleles other than those of HUMVWFA31/A, HUMTH01, D8S1179, HUMFIBRA/FGA, D21S11, D18S51.

Schumm et al. teach this limitation, see Table 1 (HUMVWFA31 and HUMTH01) and Figures 12 and 14.

**Claim 22** is drawn to a method of producing an allelic ladder or mixture thereof by subjecting the one or more alleles of Claim 17 to PCR.

Schumm et al. teach a method of producing an allelic ladder or mixture thereof by subjecting one or more alleles of Claim 17 to PCR. See, for example, Column 6 and examples 1-14.

**35 U.S.C. § 103**

**10.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**11.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

**CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

**12.** Claim(s) 1-8, 10, 14-16, 19-21 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumm et al. [US Patent No. 5,599,666 (1997)] in view of Kimpton et al.(1996).

**Claim 1** is directed to an allelic ladder mixture comprising one or more allelic ladders selected from a defined group which includes an allelic ladder for HUMVWFA31/A, HUMTH01, D8S1179, HUMFIBRA/FGA, D21S11, D18S51 which comprises a particular sequence or a sequence at least 75% homologous thereto.

Schumm et al. teach an allelic ladder comprising HUMVWFA31/A and/or HUMTH01. Admittedly, Schumm et al. does not teach the exact alleles recited in Claim 1 other than to say that the repeat comprising the HUMTH01 locus is AATG and the repeat comprising the HUMTH01 locus is AGAT. However, without defining the method (i.e. algorithm) used to determine homology it can be asserted, absent a showing to the contrary, that one of the allelic ladders taught by Schumm et al. comprises an allele for the HUMTH01 locus that is at least 75% homologous to the HUMTH01 allelic sequence recited in Claim 1 and that one of the allelic ladders taught by Schumm et al. comprises an allele for the HUMVWFA31/A locus that is at least 75% homologous to the HUMVWFA31/A allelic sequences recited in

Claim 1. This rejection is made in view of the ambiguity of Claim 1, specifically, in view of the ambiguity of the phrase "at least 75% homologous thereto". Schumm et al. is silent as regards the other allelic ladders recited (i.e. D8S1179, HUMFIBRA/FGA, D21S11, D18S51). However, Kimpton et al. do teach the amplification and use of the D8S1179, HUMFIBRA/FGA, D21S11, D18S51 tandem repeats for the identification of an individual. Therefore, absent of an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein allelic ladders for any of HUMVWFA31/A, HUMTH01, D8S1179, HUMFIBRA/FGA, D21S11, D18S51 are included. The ordinary artisan would have been motivated to combine Schumm et al. with Kimpton et al. in order to rapidly and easily identify the alleles of the loci recited in Kimpton et al. and /or to expand the number of loci which can be examined using the methodology of Schumm et al.

**Claim 2** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein the mixture includes allelic ladders for a plurality of loci which loci are selected from HUMVWFA31/A, HUMTH01, D8S1179, HUMFIBRA/FGA, D21S11, D18S51.

Note that Schumm et al. teach utilizing an allelic ladder which comprises allelic ladders for a plurality of loci. See Schumm et al., for example in Column 10.

**Claim 3** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein the mixture includes allelic ladders for at least four loci.

Admittedly, Schumm et al. do not teach a mixture which comprise allelic ladders for at least four loci. However, Schumm et al. do teach a mixture which comprises allelic ladders for at three loci. Therefore, absent of an unexpected result or a showing to the contrary, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein the mixture comprises allelic ladders for four or more loci. The ordinary artisan would have been motivated to modify the allelic ladder mixture of Schumm et al. wherein the mixture comprises allelic ladders for four or more loci in order to simultaneously evaluate multiple amplification reactions on a single gel with the minimum amount of work (i.e. gel preparation / loadings).

**Claim 4** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein the mixture includes alleles derived from the amelogenin sex test.

Admittedly, Schumm et al. do not teach that their allelic ladder mixtures should comprise alleles derived from the amelogenin sex test. However, Kimpton et al. do teach the amplification of alleles derived from the amelogenin sex test. Therefore, absent of an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein their mixtures comprise alleles derived from the amelogenin sex test.



The ordinary artisan would have been motivated to modify the allelic ladder mixture(s) of Schumm et al. wherein alleles derived from the amelogenin sex test in order to quickly and easily determine the sex of the individual being tested. Absent a showing to the contrary, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein alleles from any known polymorphic locus was included.

**Claim 5** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein the allelic ladders in the allelic ladder mixture comprises at least seven alleles.

Note that Schumm et al. teach this limitation wherein these authors teach utilizing an allelic ladder mixture which comprises allelic ladders for a plurality of loci (i.e. HUMCSF1PO, HUMFESFPS, and HUMTH01) all of which allelic ladders comprise at least seven allele. See Schumm et al., Figure 17 and examples 17, 2, 8, and 12.

**Claim 6** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein the ladders, if they are present in the mixture, are provided at a particular number, for example, such that the HUMTH01 allelic ladder comprises at least 7 alleles.

Schumm et al. teach this embodiment, see, for example, figure 12 wherein these authors the allelic ladder mixture for the HUMTH01 locus which mixture comprises at least seven alleles from this locus.

**Claim 7** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein one or more of the allelic ladders in the mixture comprise at least 4 alleles 4bp from each other.

As argued above Schumm et al. teach this embodiment see for example figure 12 wherein these authors the allelic ladder mixture for the HUMTH01 locus which mixture comprises at least seven alleles from this locus all of which are 4bp from each other, note that the repeat at the HUMTH01 is 4bp long (i.e. AATG).

**Claim 8** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein the ladders, if they are present in the mixture, are provided at a particular number, for example, such that the HUMTH01 allelic ladder comprises at least 5 alleles, 4bp from each other or such that the HUMVWFA31/A allelic ladder comprises at least 7 alleles, 4bp from each other.

Schumm et al. teach this limitation, see for example Figure 12, wherein these authors teach the allelic ladder mixture for the HUMTH01 locus which mixture comprises at least seven alleles from this locus all of which are 4bp from each other, note that the repeat at the HUMTH01 is 4bp long (i.e. AATG). See also Figure 14, wherein these authors the allelic ladder mixture for the HUMVWFA31/A locus which

mixture comprises at least 7 alleles from this locus all of which are 4bp from each other. Note that the repeat at the HUMVWFA31/A is 4bp long (i.e. AGAT).

**Claim 10** is drawn to an embodiment of the allelic ladder mixture of Claim 1 wherein the allelic ladders, if they are present in the mixture, are provided at a particular size, for example, such that the HUMTH01 allelic ladder includes alleles ranging from 150 bp to 189bp or such that the HUMVWFA31/A allelic ladder includes alleles ranging from 130 bp to 166bp. Note that the language used does not limit the claim to the range recited. It only requires that at least one "rung" of the allelic ladder fall within the range set forth.

Schumm et al. teach this limitation. See, for example, Figures 12 wherein these authors teach the allelic ladder mixture for the HUMTH01 locus which allelic ladder includes alleles ranging from 150 bp to 189bp. See also Figure 14, wherein these authors teach the allelic ladder mixture for the HUMVWFA31/A locus which allelic ladder includes alleles in the range from 130 bp to 166bp.

**Claim 14** is drawn to a method of analyzing a sample which comprises three steps. To begin, genomic DNA is obtained from the sample. Next, the DNA is subjected to amplification and finally the amplification products evaluated by comparing said products to an allelic ladder mixture wherein the allelic ladder mixture comprises one or more allelic ladders selected from a defined group which includes an allelic ladder for HUMVWFA31/A, HUMTH01, D8S1179, HUMFIBRA/FGA, D21S11, D18S51 which comprises a particular sequence or a sequence at least 75% homologous thereto.

Schumm et al. teach a method comprising the three required steps including comparing the amplification products with an allelic ladder comprising HUMVWFA31/A and/or HUMTH01. Admittedly, Schumm et al. does not teach the exact alleles recited in Claim 1 other than to say that the repeat comprising the HUMTH01 locus is AATG and the repeat comprising the HUMTH01 locus is AGAT. However, without defining the method (i.e. algorithm) used to determine homology it can be asserted, absent a showing to the contrary, that one of the allelic ladders taught by Schumm et al. comprises an allele for the HUMTH01 locus that is at least 75% homologous to the HUMTH01 allelic sequence recited in Claim 1 and that one of the allelic ladders taught by Schumm et al. comprises an allele for the HUMVWFA31/A locus that is at least 75% homologous to the HUMVWFA31/A allelic sequences recited in Claim 1. This rejection is made in view of the ambiguity of Claim 14, specifically, in view of the ambiguity of the phrase "at least 75% homologous thereto". Schumm et al. is silent as regards the other allelic ladders recited (i.e. D8S1179, HUMFIBRA/FGA, D21S11, D18S51). However, Kimpton et al. do teach the amplification and use of the D8S1179, HUMFIBRA/FGA, D21S11, D18S51 tandem repeats for the identification of an individual. Therefore, absent of an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein allelic ladders for any of HUMVWFA31/A, HUMTH01, D8S1179,

HUMFIBRA/FGA, D21S11, D18S51 are included. The ordinary artisan would have been motivated to combine Schumm et al. with Kimpton et al. in order to rapidly and easily identify the alleles of the loci in recited in Kimpton et al. and/or to expand the number of loci which can be examined using the methodology of Schumm et al.

**Claim 15** is drawn to an embodiment of the method recited in Claim 14 wherein the sample is obtained from a defined group of locations which includes a reference sample. Schumm et al. teaches this limitation. See for example, Column 6, beginning at about line 30.

**Claim 16** is drawn to an embodiment of the method recited in Claim 14 wherein the sample is amplified using PCR and the primers for one or more loci which loci include HUMVWFA31/A, HUMTH01. Schumm et al. teaches this limitation. See, for example, Table 1 and Figures 12 and 14.

**Claim 19** is drawn to the use of an allelic ladder as recited in Claim 1 for the comparison with a DNA analysis result.

As argued previously, Schumm et al. teach this limitation.

**Claim 20** is drawn to the use of an allelic ladder as recited in Claim 19 wherein said DNA analysis is a DNA profile of a sample and the profile is based on analysis of one or more loci selected from a defined group which includes HUMVWFA31/A, HUMTH01.

As argued previously, Schumm et al. teach this limitation.

**Claim 21** is drawn to a method of producing an allelic ladder or mixture thereof by subjecting the ladder of Claim 1 to PCR.

Schumm et al. teach all of the limitations of the method recited in Claim 21 wherein Schumm et al. teach subjecting their allelic ladders or mixture thereof to PCR. See, for example, Column 6 and examples 1-14.

**13. Claim(s) 9** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumm et al. [US Patent No. 5,599,666 (1997)] in view of Kimpton et al. (1996) as applied to Claim 8 above, and further in view of Sharma et al. (1992).

**Claim 9** is drawn to an embodiment of the allelic ladder mixture of Claim 8 wherein the D21S11 allelic ladder includes at least 8 alleles 8bp from each other.

Schumm et al. in view of Kimpton et al. teach all of the limitations of Claim 9 except these authors do not teach the D21S11 allelic ladder as comprising at least 8 alleles 8bp from each other. However, Sharma et al. do teach the structure of the D21S11 locus allelic ladder, as well as, the primers used to amplify this locus. In view of these teachings (i.e. Schumm et al. in view of Kimpton et al. and Sharma et al.) , and absent of an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein the allelic ladder for the D21S11 locus is included and comprises at least 8 alleles 8bp from each other. The ordinary artisan would have been motivated to make the above modification in order to quickly and easily identify the D21S11 allele amplified during a forensic test utilizing the D21S11 locus.

**14. Claim(s) 11** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumm et al. [US Patent No. 5,599,666 (1997)] in view of Kimpton et al.(1996), Barber et al. (1996) and Budowle et al. (1991).

**Claim 11** is directed to an allelic ladder mixture comprising one or more allelic ladders selected from a defined group which includes an allelic ladder for HUMVWFA31/A, HUMTH01, D8S1179, HUMFIBRA/FGA, D21S11, D18S51 wherein each loci has a designated upper and/or lower molecular weight allele. For example, the D8S1179 allelic ladder is to have an upper molecular weight allele of 19 and/or a lower molecular weight allele of 7.

Schumm et al. teach allelic ladders comprising HUMVWFA31/A and/or HUMTH01. Admittedly, Schumm et al. do not teach using the D8S1179 allele wherein it comprises an upper molecular weight allele of 19 and/or a lower molecular weight allele of 7. Schumm et al. is also silent as regards the other loci recited. Kimpton et al. do teach the amplification and use of the HUMVWFA31/A, D8S1179, HUMTH01, HUMFIBRA/FGA, D21S11, D18S51 tandem repeats for the identification of an individual. Barber et al. teach the allelic structure for the D18S51 and D8S1179. Barber et al. teach the D8S1179 allele designated as Number 8. Note also that Budowle et al. teach the use of allelic ladders. In view of these teachings (i.e. Schumm et al. in view of Kimpton et al., Barber et al. and Budowle et al.) , and absent of an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein an allelic ladder mixture is prepared for each and every locus investigated and each allelic ladder includes each and every allele known. In claim 11, for example, since the D8S1179 allele designated as Number 8 was known, it would have been, absent of an unexpected result, prima facie obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. Wherein an allelic ladder for the D8S1179 locus and using the reasoning cited above it would have been prima facie obvious to the

ordinary artisan at the time of the invention to include in each allelic ladder mixture each and every allele known.

#### CLAIM OBJECTIONS

**15.** Claim(s) 12-13 is/are objected to because they dependent upon a rejected independent base claim, however, these claims would appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

It appears the applicant has discovered new alleles for the loci recited. If the applicant amends the claims, to make it clear that the allelic ladder mixtures are to comprise these new alleles, such claim(s) would be allowable. The examiner's position is this: Allelic ladders and their use were known. Furthermore, each of the loci recited were known as were many of their alleles. It would have been, in the examiner's opinion, absent of an unexpected result, *prima facie* obvious to the ordinary artisan at the time of the invention to modify the allelic ladder mixtures taught by Schumm et al. wherein an allelic ladder mixture is prepared for each and every locus investigated and each allelic ladder includes each and every known allele. Claims clearly setting forth that the mixture(s) and/or methods must include the newly discovered alleles would be allowable. I continue to believe that the claims, as now drawn, do not meet this goal.

#### CONCLUSION

**16.** Claim(s) 1-22 is/are rejected and/or objected to for the reason(s) set forth above.


**17.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, PhD. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for the examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general

USSN: 09/910,183  
Art Unit: 1634

13

nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



ETHAN C. WHISENANT  
PRIMARY EXAMINER